REMARKS

Reconsideration of the application is respectfully requested. Claims 11-15, 17-22, and 24-26 were previously withdrawn from consideration. New claims 27 and 28 have been added and are directed to the process of claim 4 wherein the crystalline compound is crystalline form I and II, respectively. Support for new claims 27 and 28 is found in the specification at, for example, ¶17. No new matter has been added. Claims 4-7, 27, and 28 are pending and at issue.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 4-7 have been rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. The Examiner contends that while the specification enables a process of making an amorphous compound of formula (I) from crystalline form I or II, it does not enable the use of any crystalline form of formula (I) in a process of making the amorphous form.

The rejection is traversed, and reconsideration is respectfully requested.

The pending claims are directed to a process of using crystalline forms to make an amorphous compound – i.e., making an amorphous compound of formula (I) from a crystalline form of a compound of formula (I). Hence, the pending claims are not directed to a process of making crystalline forms, but rather to a process of using crystalline forms to make an amorphous compound. The Examiner acknowledges that the specification expressly discloses two examples of crystalline starting materials that may be used in the claimed process (crystalline forms I or II of formula I). *See* Office Action at p. 3; Specification at ¶17. Additionally, the specification explicitly states that "any crystalline form, such as crystalline form I or form II of the compound of the formula I as well as any form wherein the crystalline status cannot be determined" may be used in the process of the claimed invention. *See* Specification at ¶17 (emphasis added). Hence, the specification plainly teaches that the claimed process can be successfully performed using any crystalline form of formula (I) as a starting material in the process, and that the claimed process need not be limited to the use of any one particular crystalline form of the starting compound.

Furthermore, the particular crystalline form of formula (I) is not critical to the claimed

process because it is dissolved in step (a). Hence, whatever crystalline structure a specific form has will be lost once the crystals are dissolved. Accordingly, one of ordinary skill could dissolve crystalline form I, form II, or any other crystalline form of a compound of formula (I) in step (a) of the claimed process.

Given the foregoing, the disclosure in the specification would enable one of ordinary skill in the art to make and use the claimed invention without having to perform undue experimentation. *See* MPEP §2164 ("one skilled in the art must be enabled to make and use [the invention] that [is] defined by the claim(s)"); *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). Therefore, Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §112, Second Paragraph

Clams 4-7 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite. According to the Examiner, the step of dissolving a "crystalline" compound is ambiguous because it does not specify X-ray diffraction pattern (XRDP) data for the crystal.

The rejection is traversed, and reconsideration is respectfully requested.

The definiteness requirement is satisfied if one of ordinary skill in the art would understand the full scope of the claims when read in view of the specification. *See Marley Mouldings, Ltd. v. Mikron Indus.*, 417 F.3d 1356,1359 (Fed. Cir. 2005) ("The statute is satisfied if a person skilled in the field of the invention would reasonably understand the claim when read in the context of the specification.") citing *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). As set forth above, the specification expressly states that any crystalline form of formula (I) can be used in the claimed process of making an amorphous compound of formula (I). *See* Specification at ¶17. Moreover, the particular crystalline form is not critical to the claimed process because it is dissolved in step (a). Hence, upon reading the pending claims in view of the instant specification, one of ordinary skill in the art would understand the full scope of the claimed invention, and that any

crystalline form of a formula (I) compound may be used as a starting material in the claimed process regardless of the XRDP data for the starting crystal.

Given the foregoing, claims 4-7 are not indefinite. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below

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Respectfully submitted,

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